IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* LOUIS LONGO,	)	CIVIL ACTION NO. 17-1654
Plaintiff,	)	
v.	)	
WHEELING HOSPITAL, INC., R & V ASSOCIATES, LTD., and RONALD L. VIOLI,	)	
Defendants.	)	

UNITED STATES' COMPLAINT IN INTERVENTION

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The United States of America brings this action to recover damages from false claims, payment by mistake, and unjust enrichment as a result of the conduct of Wheeling Hospital, Inc. ("Wheeling Hospital"), R & V Associates, Ltd. ("R & V"), and Ronald Violi (collectively, "Defendants"). Since at least 2007, Wheeling Hospital, under the direction and control of R & V and Violi, knowingly submitted and caused the submission of claims to the Medicare program that were false because they resulted from violations of the physician self-referral law, 42 U.S.C. § 1395nn (commonly referred to as the "Stark Law"), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"). In doing so, Defendants violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, were paid by mistake, and were unjustly enriched.

NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA, and to recover damages under the common law or equitable theories of payment by mistake and unjust enrichment.

2. Within the time frames detailed below, Wheeling Hospital, under the direction and control of R & V and Violi, systematically entered into financial relationships with referring physicians that did not satisfy any statutory or regulatory exception to the Stark Law, or that violated the AKS. As a result, since at least 2007, Defendants knowingly submitted and caused to be submitted thousands of false claims to the United States, which resulted in millions of dollars of reimbursement to Wheeling Hospital by the Medicare program for claims that were ineligible for payment because of Defendants' unlawful conduct.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

4. The Court may exercise personal jurisdiction over all Defendants under 31 U.S.C. § 3732(a) and Federal Rule of Civil Procedure 4 because at least defendants R & V and Violi transact business in this district, defendant R & V is headquartered here, and defendant Wheeling Hospital has purposely directed its business activities at this forum and has continuous and systematic contacts with this forum, including by hiring R & V and Violi and by treating patients who reside in the district.

5. Venue is appropriate in this District under 28 U.S.C. § 1391(b), because at least defendants R & V and Violi transact business in this district, and R & V is headquartered here.

THE PARTIES

6. Plaintiff United States, acting through the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), administers the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare").

7. Louis Longo ("Relator") is a resident of the Commonwealth of Pennsylvania. He was employed as an Executive Vice President at Wheeling Hospital from November 2011 through August 2015. In December 2017, Relator filed this action against Defendants under the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1), alleging violations of the FCA on behalf of the United States.

8. Defendant Wheeling Hospital, Inc. is a 247-bed acute care hospital located at 1 Medical Park, Wheeling, WV 26003. It is a non-profit entity incorporated in West Virginia and owned by the Roman Catholic Diocese of Wheeling-Charleston. Wheeling Hospital provides healthcare services to patients from West Virginia, Ohio, and Pennsylvania, including from this District.

9. Defendant R & V Associates, Ltd. is a business consulting and management firm located at 310 Grant Street, Suite 1120, Pittsburgh, PA 15219. It is a limited liability corporation founded by its two principals, defendant Ronald Violi (a business executive) and Vincent Deluzio (an attorney). R & V has served as Wheeling Hospital's management consultant since around 2006. In that capacity, R & V has been in charge of a wide range of management functions at the hospital, including executive leadership, financial oversight, legal strategy, regulatory compliance, and staffing decisions including physician recruitment and physician-practice acquisition. For purposes of this lawsuit, in all respects concerning R & V's management and oversight of Wheeling Hospital, R & V's scienter and actions were imputable to the hospital.

10. Defendant Ronald Violi is a resident of the Commonwealth of Pennsylvania and this District. He is a principal and managing director of defendant R & V. Since 2006, pursuant to Wheeling Hospital's retention of R & V, he has served as the hospital's Chief Executive Officer ("CEO"), made all physician retention decisions, and negotiated and signed all of the hospital's physician contracts. For purposes of this lawsuit, in all respects concerning Violi's management and oversight of Wheeling Hospital, his scienter and actions were imputable to both Wheeling Hospital and R & V.

LEGAL AND REGULATORY BACKGROUND

I. The False Claims Act

11. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .

> (a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains[.]

31 U.S.C. § 3729.[1]

12. For purposes of the False Claims Act,

> the term "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information; and require no proof of specific intent to defraud.

31 U.S.C. § 3729(b).

13. The False Claims Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," 31 U.S.C. § 3729(b)(4).

[1] The FCA was amended by Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Given the nature of the claims at issue, Section 3279(a)(1), (a)(2), and (a)(7) of the prior statute, and Section 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G) of the revised statute all apply here. Section 3729(a)(1) and (a)(7) apply to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) and (a)(1)(G) apply to conduct after FERA was enacted. By virtue of Section 4(f) of FERA, Section 3729(a)(2) applies to all claims in this case paid before June 7, 2008, and Section 3729(a)(1)(B) applies to all claims pending for payment thereafter.

II. The Medicare Program

14. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services. HHS is responsible for administering and supervising the Medicare program. CMS is a component of HHS and is directly responsible for administering the Medicare program.

15. At all times relevant to this lawsuit, except where a different time period is specified, the following statutory and regulatory rules applied to the Medicare program:

16. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A.

17. The Medicare regulations define a "provider" to include "a hospital . . . that has in effect an agreement to participate in Medicare." 42 C.F.R. § 400.202.

18. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

19. There are four Parts to the Medicare Program: Part A authorizes payment for institutional care, including inpatient hospital care, skilled nursing facility care, and home health care, *see* 42 U.S.C. §§ 1395c-1395i-4; Part B primarily covers outpatient care, including physician services and ancillary services, *see* 42 U.S.C. § 1395k; Part C is the Medicare Advantage Program, which provides Medicare benefits to certain Medicare beneficiaries through private health insurers, *see* 42 U.S.C. § 1395w-21 *et seq.*; and Part D provides prescription drug coverage, *see* 42 U.S.C. § 1395w-101 *et seq.*; 42 C.F.R. § 423.1 *et seq.*

20. Since November 2006, CMS has contracted with Medicare Administrative Contractors ("MACs") to assist in the administration of Medicare Parts A and B. *See* Fed. Reg. 67960, 68181 (Nov. 2006). MACs generally act as CMS's agents in reviewing and paying Part A

and Part B claims submitted by healthcare providers and perform administrative functions on a regional level. *See* 42 C.F.R. § 421.5(b); *see also* 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104.

21. Under the Medicare program, CMS (through MACs) makes payments prospectively for hospital inpatient services, through periodic payments and the cost-report reconciliation process described below, and retrospectively for hospital outpatient services, after the services are rendered.

22. Upon discharge of Medicare beneficiaries from a hospital, the hospital submits Medicare Part A claims for reimbursement for inpatient items and services delivered to those beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Inpatient services are paid using the Inpatient Prospective Payment System. In addition, designated hospital outpatient items and services are paid under the Outpatient Prospective Payment System. Hospitals submit claims for Medicare reimbursement using the electronic claim form known as the 837I or its paper equivalent, Form CMS-1450 (also known as the UB-04). The claim form instructions, found in Chapter 25, section 75 of the Claims Processing Manual, set forth the Medicare requirements for use of the various codes in completing the form.

23. When physicians provide patient care services in a hospital setting, whether to hospital inpatients or outpatients, they (or an entity to which they have assigned billing rights) may bill Medicare for their "professional" services, which include performing procedures and interpreting test results, using a CMS Form 1500. The hospital may submit a separate claim to Medicare for the "technical" or "facility" component of the services rendered, as described in the preceding paragraph, under which the hospital is reimbursed for furnishing, among other things, equipment and non-physician staff.

24. Providers must be enrolled in Medicare in order to be reimbursed by the Medicare program. *See* 42 C.F.R. § 424.505. To enroll in Medicare, institutional providers such as hospitals periodically must complete a Medicare Enrollment Application (often called a Form CMS-855A). In completing the Medicare Enrollment Application, an institutional provider certifies:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. ***I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law)***, and on the provider's compliance with all applicable conditions of participation in Medicare (emphasis added).

The Medicare Enrollment Application also summarizes the False Claims Act in a separate section that explains the penalties for falsifying information in the application to "gain or maintain enrollment in the Medicare program."

25. Medicare enrollment regulations further require providers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

26. As a prerequisite to Medicare payment under Medicare Part A, CMS also requires hospitals to submit annually a form CMS-2552, commonly known as a hospital cost report. A cost report is the final claim that a provider submits to a MAC for items and services rendered to Medicare beneficiaries during the year covered by the report.

27. After the end of each of a hospital's fiscal years, the hospital files its hospital cost report with the MAC, stating the amount of Part A reimbursement the provider believes it is due for the year, or the amount of excess reimbursement it has received through interim payments

during the year that it owes back to Medicare. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. *See also* 42 C.F.R. § 405.1801(b)(1). Medicare relies upon the hospital cost report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. *See* 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1).

28. Medicare Part A payments for Social Security Act section 1886(d) hospital services, *see* 42 U.S.C. § 1395ww, are determined under a prospective payment system using the claims submitted by the provider for particular patient discharges (specifically listed on UB-92s and UB-04s) during the course of the fiscal year. On the hospital cost report, the prospective payments for services are added to any other Medicare Part A add-on payments due to the provider. This total determines Medicare's liability for services rendered to Medicare Part A beneficiaries during the course of a fiscal year. From this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare Part A program or the amount due the provider.

29. Every hospital cost report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

30. That chief administrator or designee is required to certify, in pertinent part:

> [T]o the best of my knowledge and belief, it [the hospital cost report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

31. The hospital cost report certification page also includes the following notice:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and

> administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

32. Thus, a provider must certify (1) that the filed hospital cost report is truthful, i.e., that the cost information contained in the report is true and accurate; (2) that it is correct, i.e., that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) that it is complete, i.e., that the hospital cost report is based upon all information known to the provider; and (4) that the services provided in the cost report were billed in compliance with applicable laws and regulations, including the Stark Law and AKS.

33. A hospital is required to disclose all known errors and omissions in its claims for Medicare Part A reimbursement (including its cost reports) to its MAC.

34. Medicare, through its MACs, has the right to audit a provider hospital's cost reports and financial representations to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to hospital cost reports previously submitted by a provider if any overpayments have been made. *See* 42 C.F.R. § 413.64(f).

III. The Stark Law

35. Enacted as amendments to the Social Security Act, the physician self-referral law, commonly referred to as the "Stark Law," prohibits hospitals and other entities providing "designated health services" ("DHS"), as defined in 42 U.S.C. § 1395nn(h)(6) and 42 C.F.R. § 411.351, from submitting Medicare claims for such services as a result of patient referrals from a physician who has a "financial relationship" (as defined in the statute and regulations) with the

hospital that does not satisfy the requirements of an applicable exception, and prohibits Medicare from paying such claims.

36. As initially enacted in 1989, the Stark Law applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992, by a physician to a laboratory with which the physician had a financial relationship unless a statutory or regulatory exception applied. *See* Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204. In 1993, Congress extended the Stark Law's application to referrals for ten additional DHS. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, § 13562, Social Security Act Amendments of 1994, P.L. 103-432, § 152. In 2008, Congress added outpatient speech-language pathology services to the list of DHS. *See* Medicare Improvements for Patients and Providers Act of 2008, P.L. 110-275, § 143.

37. The Stark Law was designed specifically to prevent patient steering, stinting on care, and losses that might be suffered by the Medicare program due to questionable utilization of DHS, as well as to address costs to the healthcare system as a whole.

38. In pertinent part, the Stark Law provides:

> (a) Prohibition of certain referrals
>
> > (1) In general
> >
> > Except as provided in subsection (b) of this section, if a physician . . . has a financial relationship with an entity specified in paragraph (2), then –
> >
> > (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
> >
> > (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services

> furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1).

39. "Designated health services" include inpatient and outpatient hospital services, and radiology and laboratory services. *See* 42 U.S.C. § 1395nn(h)(6).

40. "Financial relationships" include "compensation arrangements" involving the payment of remuneration directly or indirectly to a referring physician, as defined in 42 U.S.C. § 1395nn(h)(1)(A) and (h)(1)(B) and 42 C.F.R. § 411.354(c).

41. The Stark Law explicitly states that Medicare may not pay for any DHS referred in violation of the statute. *See* 42 U.S.C. § 1395nn(g)(1). In addition, the regulations implementing the Stark Law expressly require that any entity collecting payment for DHS "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353(d) (2006).

42. The Stark Law and its companion regulations set forth exceptions for certain financial relationships that meet specific enumerated requirements. The Stark Law's exceptions operate as affirmative defenses to alleged violations of the statute. To invoke an exception successfully, a defendant bears the burden of proving compliance with every requirement of that exception.

43. The Stark Law and its companion regulations set forth exceptions for, among other things, "*bona fide* employment relationships," "personal service arrangements," "rental of equipment," and "indirect compensation arrangements."

44. To qualify for the Stark Law's exception for *bona fide* employment relationships, a compensation arrangement must meet the following requirements:

(A) the employment is for identifiable services;

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services; and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician;

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer; and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(2); *see also* 42 C.F.R. §§ 411.357(c), 411.354(d)(4).

45. To qualify for the Stark Law's exception for personal service arrangements, a compensation arrangement must meet the following statutory requirements:

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity;

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

(iv) the term of the arrangement is for at least 1 year;

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law; and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(3)(A); *see also* 42 C.F.R. §§ 411.357(d), 411.354(d)(4).

46. To qualify for the Stark Law's exception for rental of equipment, a compensation arrangement must meet the following statutory requirements:

> (i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,
>
> (ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,
>
> (iii) the lease provides for a term of rental or lease of at least 1 year,
>
> (iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
>
> (v) the lease would be commercially reasonable even if no referrals were made between the parties, and
>
> (vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(1)(B); *see also* 42 C.F.R. § 411.357(b).

47. To qualify for the Stark Law's exception for indirect compensation arrangements, a compensation arrangement must meet the following regulatory requirements:

> (1)
>
> > (i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.
> >
> > (ii) Compensation for the rental of office space or equipment may not be determined using a formula based on -
> >
> > > (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

> (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
>
> (2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.
>
> (3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

42 C.F.R. § 411.357(p); *see also* 42 C.F.R. § 411.354(d)(4).

IV. The Anti-Kickback Statute

48. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal healthcare programs from these difficult-to-detect harms, Congress enacted the AKS in 1972, imposing a per se prohibition against the payment of kickbacks in any form, without requiring proof that the particular kickback gave rise to overutilization or poor quality of care.

49. The AKS is a federal criminal statute that makes it a felony to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce referrals of individuals for services or items reimbursed in whole or in part by a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A).

50. "Willfulness" under the AKS requires that the defendant intended to violate the law, but a person "need not have actual knowledge of th[e AKS] or specific intent to commit a violation of th[e AKS]." 42 U.S.C. § 1320a-7b(h).

51. "Remuneration" under the AKS covers anything of value. *See, e.g.*, 56 Fed. Reg. 35952 (Jul. 29, 1991).

52. Medicare is a "Federal health care program" as defined in the AKS. 42 U.S.C. § 1320a-7b(f).

53. The knowing and willful payment of remuneration violates the AKS where even one purpose of that payment is to induce the referral of federal health program-related business.

54. Claims submitted to federal healthcare programs that include items or services resulting from violations of the AKS are "false" under the FCA. This rule was recognized and enforced by courts at all relevant times until 2010, at which point Congress amended the AKS to state this rule explicitly in the statute. 42 U.S.C. § 1320a-7b(g); *see also* 155 Cong. Rec. S10854 (Statement of Sen. Leahy observing that this amendment to the AKS clarifies "that all claims resulting from illegal kickbacks are considered false claims for purposes of civil action under the False Claims Act.").

55. The AKS contains statutory and regulatory "safe harbors" that protect specified arrangements from the law's reach by exempting them from the statute's definition of "remuneration." *See generally* 42 C.F.R. § 1001.952. The safe harbors operate as affirmative defenses and set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. Safe harbor protection, however, is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

56. To qualify for the AKS's safe harbor for personal services and management contracts, the arrangement must satisfy the following requirements:

(1) The agency agreement is set out in writing and signed by the parties.

> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
>
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
>
> (4) The term of the agreement is for not less than one year.
>
> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
>
> (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
>
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.
>
> For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1001.952(d).

DEFENDANTS' FRAUD SCHEME

57. In the early 2000s, Wheeling Hospital experienced financial difficulties, having lost more than $55 million from operations from 1998 to 2005.

58. In or around January 2006, Wheeling Hospital entered into a management contract with R & V to improve the hospital's financial performance. Under this arrangement, R & V provided comprehensive management, consulting, and crisis-management services. The parties have renewed their arrangement several times, at least through December 31, 2018. On information and belief, Wheeling Hospital's management arrangement with R & V remains in effect as of the date of this filing.

59. Pursuant to Wheeling Hospital's retention of R & V, Violi served as the hospital's CEO from 2006 through December 31, 2018, and, on information and belief, continuing to the present. Deluzio, Violi's partner at R & V, has also been closely involved in the management of Wheeling Hospital, including with respect to legal and compliance issues.

60. Wheeling Hospital's retention of R & V was authorized and executed by then-Bishop of Wheeling-Charleston, Michael J. Bransfield. According to the parties' contracts and letters of understanding, R & V, in its management of the hospital, reported to and took direction from Bishop Bransfield and an Ad Hoc Committee of the hospital's board of directors comprising Bishop Bransfield, Monsignor Kevin Quirk of the Diocese of Wheeling-Charleston (president of the board of the directors), and a third member of Wheeling Hospital's board of directors. Bishop Bransfield determined any monetary bonuses to be paid to R & V. R & V had the right to terminate its management arrangement with Wheeling Hospital in the event that Bransfield ceased serving as the Bishop of Wheeling-Charleston.

61. In addition to executive management functions, R & V's responsibilities under its arrangement with Wheeling Hospital included "Legal Strategy," "Regulatory Compliance," "[t]he adoption and implementation of policies and procedures necessary for legal and regulatory compliance," and "[t]he establishment of appropriate policies and procedures where lacking." R & V was also responsible for "[t]he recruitment of new physicians and other qualified medical staff," and "[t]he acquisition of physician practices."

62. Beginning in 2007, R & V's role at Wheeling Hospital expanded to include "special advisory and consulting and management services relative to the potential acquisition of Ohio Valley Medical Center," another acute-care hospital located approximately four miles from Wheeling Hospital.

63. Under Violi's and R & V's management, Wheeling Hospital went from losing money from its operations to generating substantial profits. During the hospital's first five years under Violi's and R & V's management, for example, it realized operating profits of nearly $90 million.

64. Wheeling Hospital's compensation to R & V increased steadily over the course of the parties' management arrangement. The parties' July 2007 letter of understanding provided that Wheeling Hospital would pay R & V an annual fee of $1.155 million, plus "an immediate bonus payment of $300,000 reflecting the financial success of [R & V's] consulting services," plus an "additional supplemental payment of $50,000 for special merger and acquisition services (the scope of which has been extended to other institutions as acquisition/affiliation targets)," for total annual compensation of $1.505 million. Their June 2009 letter of understanding provided for an annual fee of $2.355 million. Their June 2011 contract provided for an annual payment of $2.976 million for each year from 2012 through 2015. Their February 2015 letter provided for an extension bonus at that time of $2 million, and annual compensation for 2016 in the amount of $2 million. According to their May 2016 letter, the compensation paid by Wheeling Hospital to R & V in 2017 and 2018 increased to $3.25 million and $3.5 million, respectively. Furthermore, as originally set forth in the parties' February 2007 letter, R & V was to receive an additional $950,000 in the event of a successful acquisition of Ohio Valley Medical Center, which did not materialize.

I. Defendants' Physician Relationships

65. One of the principal means by which Violi and R & V engineered Wheeling Hospital's financial turnaround was the hiring of a large number of physicians, primarily as

employees, to capture for the hospital those physicians' referrals and the resulting revenues, thereby increasing Wheeling Hospital's market share.

66. In executing that strategy, since at least 2007, Wheeling Hospital, under the direction and control of R & V and Violi, systematically entered into compensation arrangements with referring physicians that did not satisfy the requirements of any statutory or regulatory exception to the Stark Law, or that violated the AKS. The physician compensation arrangements alleged below are some examples of this scheme.

67. In the ordinary course of Wheeling Hospital's business, Defendants regularly kept and updated "Physician Impact Reports," in which they tracked revenues for each employed and contracted physician's professional services, and, separately, the technical fees that Wheeling Hospital billed in connection with each physician's services.

68. Because all inpatient and outpatient hospital services are designated health services under the Stark Law, any technical revenues resulting from a physician's referrals to Wheeling Hospital resulted from DHS referrals, including the technical fees that Wheeling Hospital billed in connection with the physician's services. 42 U.S.C. § 1395nn(h)(5). In other words, for hospital inpatient and outpatient services, the component billed by the hospital (for "any hospital service, technical component or facility fee") is deemed a referral from the physician to the hospital. *See* 66 Fed. Reg. 856, 941 (Jan. 4, 2001).

69. During internal discussions about physician compensation, Defendants were focused heavily on the revenues generated by physicians' referrals to Wheeling Hospital. For example, in a 2008 memorandum regarding the compensation to be paid to Dr. Ahmad Rahbar (an employed cardiovascular surgeon), Jim Murdy (Wheeling Hospital's Chief Financial Officer ("CFO")) wrote, "we should all keep in mind that Rahbar is a man we need to keep happy. In

FY07 he generated over $11 million in revenues for us." Later, in a 2012 memorandum regarding physician compensation arrangements, Scott McKeets (Wheeling Hospital's Chief Operating Officer ("COO")) wrote, with respect to the possibility of amending the compensation of Dr. Chandra Swamy (an employed obstetrician-gynecologist), "I would not recommend doing so anyway as we would not want to endanger the significant downstream revenue that she produces for Wheeling Hospital."

A. Dr. Adam Tune

70. In or around 2012, Defendants determined that Wheeling Hospital could increase its profits by hiring a pain-management physician. They wanted Wheeling Hospital to hire a pain-management physician, among other things, in order to capture ancillary services referred by that physician (including DHS), and the technical fees generated from the physician's referrals.

71. During the fall of 2012, Defendants attempted to negotiate an employment agreement between Wheeling Hospital and Dr. Adam Tune, a Pittsburgh-based anesthesiologist who specialized in pain management.

72. During these negotiations, Relator (who at that time served as Wheeling Hospital's Executive Vice President) expressed concern to CFO Jim Murdy and COO Scott McKeets that Wheeling Hospital may have been considering paying Dr. Tune a salary that exceeded the fair market value of his services.

73. Following that discussion, on November 27, 2012, Murdy sent an email to McKeets and Relator with a link to an article describing an investigation by the U.S. Department of Justice into whether a Florida Hospital had entered into compensation arrangements with physicians that did not satisfy any exception to the Stark Law.

74. Around late 2012 or early 2013, Defendants' employment negotiations with Dr. Tune fell through without the execution of any final agreement.

75. Thereafter, Defendants and Dr. Tune negotiated – and, on June 4, 2013, Violi and Dr. Tune executed – a different kind of arrangement, under which Dr. Tune would lease clinic space on Wheeling Hospital's campus where he would operate an independent pain-management clinic.

76. In February 2013, during these lease negotiations, Dr. Tune incorporated a legal entity for his planned clinical practice called Three Rivers Pain and Anesthesia Associates, PLLC ("Three Rivers"), with himself as the sole owner.

77. In late July 2013, while the renovation of Dr. Tune's clinic on Wheeling Hospital's campus was under way, but before the clinic was operational, Defendants and Dr. Tune came to disagree over an issue relating to the billing of the services to be performed at Dr. Tune's clinic.

78. Specifically, Dr. Tune planned to bill a global physician practice fee for all services he provided at his clinic, in accordance with typical physician-office practices. Defendants, however, assumed and insisted that Wheeling Hospital would bill for the technical fees generated by Dr. Tune's services.

79. Violi told Dr. Tune that Wheeling Hospital was not interested in pursuing the parties' executed lease arrangement if it could not bill for the technical fees generated by Dr. Tune's services. The parties therefore terminated their June 4, 2013 lease agreement.

80. Thereafter, the parties negotiated – and, on August 19, 2013, Violi and Dr. Tune executed – an agreement under which Wheeling Hospital would retain Dr. Tune as an independent contractor to furnish services in a pain-management clinic (the construction of

which had been nearly completed, pursuant to the planned lease arrangement) on Wheeling Hospital's campus and behalf. Under this arrangement, Wheeling Hospital had the right to (and did) bill for the professional services that Dr. Tune provided, as well as the facility fees (i.e., the technical components) for the services that Wheeling Hospital provided in connection with Dr. Tune's services.

81. The "Compensation" paragraph in the parties' August 19, 2013 contract specified that Dr. Tune "may charge [Wheeling] Hospital at the rate of Three Thousand Dollars ($3,000.00) per each day for which [he] see[s] patients for a minimum of eight (8) hours at Medical Park [i.e., Wheeling Hospital]. In addition, [Dr. Tune] is eligible to receive an incentive at the rate of Seventy [percent] (70%) of the 'Net Income' of the practice."

82. The contract defined "Net Income," for purposes of calculating Dr. Tune's incentive compensation, as "accrual basis total net operating revenue" minus "all ordinary, necessary, and reasonable costs and expenses." It clarified that "Revenue shall include all professional and technical revenue generated by [Dr. Tune] regardless of where the service is performed," and that Dr. Tune "shall receive revenue for services performed in the office, inpatient, and in the Department of Radiology."

83. Shortly after Wheeling Hospital and Dr. Tune entered into this contract, Murdy (Wheeling Hospital's CFO) told McKeets (the COO) that he had concerns about the legality of Wheeling Hospital's payment to Dr. Tune of incentive compensation tied to the technical fees that Dr. Tune generated for Wheeling Hospital.

84. In or around early or mid-2015, Wheeling Hospital's General Counsel, Bruce Archer, told Dr. Tune that, because of legal concerns regarding the hospital's payment to Dr.

Tune of incentive compensation as described in the parties' contract, they would have to amend his contract to remove that language.

85. Notwithstanding those concerns, through the end of 2015, Wheeling Hospital continued to pay Dr. Tune incentive compensation pursuant to the parties' August 2013 contract.

86. In fact, even after Archer expressed to Dr. Tune the concerns described above, Wheeling Hospital (through Violi and R & V) and Dr. Tune executed two addenda to the parties' August 2013 agreement – in August and September 2015 – extending the original contract through December 31, 2015.

87. Eventually, on January 1, 2016, Wheeling Hospital (through Violi and R & V) and Dr. Tune signed a new contract. This contract removed Dr. Tune's incentive compensation, but more than doubled his daily stipend, from $3,000 to $6,100.

88. Wheeling Hospital calculated and intended the 2016 increase to Dr. Tune's daily stipend to make up for his removed incentive compensation, which it approximately did.

89. Despite the fact that the 2013 and 2016 contracts described above were between Wheeling Hospital and Dr. Tune, the hospital paid the compensation described therein to Dr. Tune's wholly owned incorporated practice, Three Rivers.

90. Wheeling Hospital's total annual compensation to Three Rivers from 2013 through 2018 was approximately $153,000 (August to December, 2013), $1.59 million (2014), $1.54 million (2015), $1.46 million (2016), $1.42 million (2017), and $1.43 million (2018).

91. Of those amounts, after Three Rivers paid the salaries of Dr. Tune's clinic staff and other costs, Dr. Tune personally took home salaries of around $1 million to $1.2 million per year from 2014 through 2018. During this time, the nationwide 50th percentile for

pain-management physicians' annual salaries ranged from approximately $415,000 to $450,000, and the 90th percentile ranged from approximately $700,000 to $750,000.

92. Violi and R & V caused Wheeling Hospital to enter into the above-described contracts with Dr. Tune, and to pay Dr. Tune under those arrangements.

93. Wheeling Hospital knowingly and willfully paid Dr. Tune – and Violi and R & V knowingly and willfully caused Wheeling Hospital to pay Dr. Tune – remuneration under these compensation arrangements to induce Dr. Tune to make referrals to Wheeling Hospital of services reimbursable by federal healthcare programs in violation of the AKS.

94. By virtue of their 2013 and 2016 contracts, Wheeling Hospital and Dr. Tune had a compensation arrangement under the Stark Law. *See* 42 C.F.R. § 411.351 (defining "Physician" to include a "professional corporation of which he or she is a sole owner"). Throughout the existence of these compensation arrangements, Dr. Tune made DHS referrals to Wheeling Hospital (including inpatient and outpatient hospital services), for which Wheeling Hospital submitted claims to, and received payments from, Medicare.

95. Wheeling Hospital's compensation arrangements with Dr. Tune failed to satisfy an applicable exception to the Stark Law, because, at a minimum, the compensation paid by Wheeling Hospital to Dr. Tune exceeded the fair market value of the services he provided and was determined in a manner that took into account the volume or value of his DHS referrals to, and other business generated for, Wheeling Hospital. 42 U.S.C. § 1395nn(e)(3)(A); 42 C.F.R. § 411.357(d). Wheeling Hospital's submission of claims to Medicare for payment for DHS referred to the hospital by Dr. Tune thus violated the Stark Law.

96. Wheeling Hospital's payments to Dr. Tune failed to satisfy any applicable AKS safe harbor because, at a minimum, that compensation was not consistent with fair market value

in an arms-length transaction and was determined in a manner that took into account the volume or value of Dr. Tune's referrals to the hospital of services reimbursable by federal healthcare programs, *see* 42 C.F.R. § 1001.952(d).

B. Employed Physicians

97. As explained above, under Violi's and R & V's control, Wheeling Hospital greatly increased its number of employed physicians. Following his appointment as CEO, Violi personally negotiated and signed all of Wheeling Hospital's physician contracts. Deluzio (Violi's partner at R & V) and Archer (Wheeling Hospital's general counsel) typically assisted Violi in negotiating physician contracts.

98. Under these employment contracts, Wheeling Hospital had the right to, and did, bill for the professional fees for services furnished by its employed physicians and the technical revenues generated by its employed physicians' referrals to Wheeling Hospital.

99. Under Violi's and R & V's control, Wheeling Hospital systematically paid employed physicians incentive compensation in the form of a percentage of what Defendants calculated to be the "net revenue" or "net income" attributable to that physician, as detailed below.

100. Unlike its 2013 personal service arrangement with Dr. Tune, Wheeling Hospital's employment contracts typically did not define how the hospital calculated the "net income" or "net revenue" attributable to a given physician. As a rule, however, under Violi's and R & V's direction and control, the hospital did so in substantially the same way it did with Dr. Tune. That is, in calculating the "net revenue" or "net income" attributable to an employed physician for purposes of calculating that physician's incentive compensation, Wheeling Hospital included technical fees billed by the hospital in connection with the employed physician's services.

101. Wheeling Hospital paid at least 36 of its employed physicians such incentive compensation.

102. In or around 2012, Wheeling Hospital created a spreadsheet detailing its compensation arrangements with all of its employed physicians at that time. For each physician, that spreadsheet listed, among other things: the physician's specialty; the date that the physician began his or her employment at Wheeling; the physician's base salary; and the terms of any physician incentive compensation. This spreadsheet listed 59 employed physicians, of whom at least 36 were listed as having employment contracts that provided for compensation tied to what Defendants calculated as the "net revenue" or "net income" attributable to that physician.

103. Under Violi's and R & V's direction and control, Wheeling Hospital entered into other physician employment arrangements (both before and after the spreadsheet described above was created) with similar compensation provisions since 2007.[2]

104. The following physicians are some specific examples of those who had employment arrangements with Wheeling Hospital that provided for compensation tied to the volume or value of the physician's referrals of designated health services to the hospital:

[2] Wheeling Hospital's press releases confirm that the hospital has continually hired physicians as employees since 2006, https://wheelinghospital.org/about/news/archive.aspx?s=&t=0 (last visited Mar. 21, 2019), including in 2013 and beyond. The hospital's physician salaries, available at the West Virginia Health Care Authority's website, https://hca.wv.gov/Pages/default.aspx, show that a number of those physicians' salaries fluctuated substantially from year to year.

Physician	Specialty	Employment period
Akhavan-Heidari, Mehdi	Cardiac surgery	2009-2016
Alkhouri, Nabiel	Medical oncology	2007-2012
Andreini, Hugo	Urology	2010-2018
Maevsky, Victor	Cardiac surgery	2009-present
Mascarenhas, Christopher	Colorectal surgery	2012-2016
Millit, H. David	Cardiology	2003-2016
Rahbar, Ahmad	Cardiac surgery	2009-2016
Schmitt, Bradley	Internal medicine	2004-present
Shinn, Lowell	Medical oncology	2012-present
Swamy, Chandra	OB/GYN	2009-present
Wolen, John	General surgery	2011-2016
Ybanez-Morano, Jessica	OB/GYN	2008-2014
Zilles, Michael	Orthopedic surgery	2011-2015

105. Violi and R & V caused Wheeling Hospital to enter into the above-described compensation arrangements with employed physicians, and to pay those physicians the compensation described under those arrangements.

106. Wheeling Hospital's physician employment relationships qualified as compensation arrangements under the Stark Law. Throughout the existence of those employment relationships, each of the employed physicians listed above, and many others (including many who received similar compensation), made referrals to Wheeling Hospital, as a result of which the hospital submitted claims to Medicare for DHS.

107. Defendants' compensation arrangements with physicians who received incentive compensation in the form of a percentage of the "net revenue" or "net income" attributable to their DHS referrals did not satisfy the requirements of an applicable exception to the Stark Law because, at a minimum, the amount of the remuneration under their employment was determined in a manner that took into account (directly or indirectly) the volume or value of their DHS referrals to Wheeling Hospital. 42 U.S.C. § 1395nn(e)(2)(B); 42 C.F.R. § 411.357(c). Wheeling Hospital's submission of claims to Medicare for payment for DHS referred to the hospital by the

physicians with whom the hospital had such compensation arrangements thus violated the Stark Law.

C. Radiology Associates

108. Radiology Associates, Inc. ("RAI") is a physician practice group that provides radiological services at Wheeling Hospital.

109. The physicians of RAI collectively own all of the shares in an investment entity called Radiology Associates of Wheeling, LLC ("RAW"). RAW, in turn, owns a 50 percent interest in an entity called Insight Imaging – Upper Ohio Valley, LLC ("IUOV").

110. Since March 17, 2008, Wheeling Hospital has had a contractual arrangement with IUOV through which the hospital rented magnetic resonance imaging ("MRI") equipment from IUOV. Pursuant to that arrangement, Wheeling Hospital pays IUOV a predetermined fee each time it uses the rented MRI equipment to perform an imaging test.

111. From March 17, 2008, through July 2018, RAI physicians themselves ordered nearly 100 MRI tests for Medicare beneficiaries at Wheeling Hospital on the equipment rented from IUOV. As a result of those physicians' ownership of RAW, RAW's ownership of IUOV, and IUOV's MRI rental arrangement with Wheeling Hospital, each of those tests resulted in a payment from Wheeling Hospital to the ordering radiologist and his or her fellow RAI physicians.

112. Dr. Vincent Caruso, one of RAI's partner physicians, ordered the largest number of such MRIs (approximately 75).

113. Wheeling Hospital entered into the above-described rental arrangement with IUOV and made the payments described under that arrangement – and Violi and R & V caused the hospital to do so – with knowledge of the RAI physicians' ownership interest in IUOV.

114. Wheeling Hospital's equipment rental arrangement with IUOV qualified as a financial relationship under the Stark Law – specifically, as an indirect compensation arrangement between the hospital and each physician owner of RAW, because (i) there was an unbroken chain of entities in financial relationships (ownership or compensation) with each other (Wheeling Hospital to IUOV, to RAW, to each physician owner of RAW); (ii) as a result of Wheeling Hospital's arrangement with IUOV, each physician received compensation that varied with, or took into account, the volume or value of referrals or other business generated by the referring physician for Wheeling Hospital; and (iii) Wheeling Hospital had actual knowledge, or acted with reckless disregard or deliberate ignorance of the fact, that the RAI physicians received such compensation. 42 C.F.R. § 411.354(c)(2).

115. Throughout the existence of this indirect compensation arrangement, these radiologists made referrals of designated health services to Wheeling Hospital, as a result of which Wheeling Hospital submitted claims to Medicare.

116. Wheeling Hospital's indirect compensation arrangements with each of the physician owners of RAW did not meet the requirements of an applicable exception to the Stark Law because, at a minimum, the rental charges paid by Wheeling Hospital over the term of the lease were determined using a formula based on a per-unit of service rental charge that reflected services provided to patients referred by the physician owners of RAW to the hospital. 42 C.F.R. § 411.357(p). Wheeling Hospital's submission of claims to Medicare for payment for DHS referred to the hospital by these physicians thus violated the Stark Law.

II. Defendants' False Claims and Statements

117. Wheeling Hospital submitted, and Violi and R & V caused it to submit, claims for specific inpatient and outpatient hospital services provided to individual Medicare beneficiaries

referred by the physicians with whom the hospital had the compensation arrangements described above.

118. At all times relevant to this lawsuit, the Medicare statutory and regulatory rules described above, *see supra* pp. 3-16, applied to Wheeling Hospital as an enrolled Medicare provider.

119. From before 2006 through June 19, 2011, United Government Services, LLC served as the MAC to which Wheeling Hospital submitted Medicare enrollment forms, claims, and cost reports. Since June 20, 2011, and continuing through the present, West Virginia – Palmetto GBA has served as the MAC to which Wheeling Hospital has submitted Medicare enrollment forms, claims, and cost reports.

120. Throughout the relevant time period, Wheeling Hospital submitted, and Violi and R & V caused the hospital to submit, Medicare enrollment applications, including on October 17, 2011, February 24, 2016, and March 13, 2018. Violi and CFO Jim Murdy signed the certification pages on all three of those example enrollment applications.

121. In those enrollment applications, Defendants certified, among other things:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. ***I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law)***, and on the provider's compliance with all applicable conditions of participation in Medicare (emphasis added).

122. Throughout the relevant time period, Wheeling Hospital submitted, and Violi and R & V caused the hospital to submit, annual Medicare cost reports as described above, including on February 27, 2009, March 30, 2012, February 25, 2015, and February 23, 2018. Of those

examples, CFO Jim Murdy signed the certification pages of every cost report except for the one dated February 23, 2018, which was signed by COO Scott McKeets.

123. In its cost reports, Wheeling Hospital certified, and Violi and R & V caused the hospital to certify:

> [T]o the best of my knowledge and belief, it [the hospital cost report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

124. Wheeling Hospital's cost-report certification pages also included the following notice:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

125. Defendants expressly and falsely certified compliance with the Stark Law and the AKS in Wheeling Hospital's annual cost reports, which, as explained above, constituted the hospital's final claim for items and services provided to Medicare beneficiaries for that year.

126. Wheeling Hospital also submitted, and Violi and R & V also caused the hospital to submit, thousands of Medicare claims for specific services unlawfully referred in violation of the Stark Law and AKS.

127. In submitting such claims, Wheeling Hospital made, and Violi and R & V caused the hospital to make, specific representations about the billed services that were rendered materially misleading by Defendants' knowing failure to disclose the claims' noncompliance

with the Stark Law and the AKS. Specifically, and among other things, such claims identified the physician(s) who had referred the services billed for without disclosing that the hospital's remuneration to such physician(s) rendered those referrals and claims unlawful.

128. The following are specific examples of claims for inpatient and outpatient hospital services, submitted by Wheeling Hospital and caused by Violi and R & V, that resulted from referrals by the physicians described above[3]:

[3] The United States will provide detailed information concerning these example claims to Defendants upon entry of an appropriate protective order.

Patient	Referring Physician	Inpatient DRG	Dates of Service	Reimbursement
1	Alkhouri, Nabiel	Acute myocardial infarction, expired with major complications or comorbidities	1/4/12 - 1/15/12	$18,657.74
2	Andreini, Hugo	Transurethral procedures with complications or comorbidities	12/12/14 - 12/19/14	$7,585.97
3	Mascarenhas, Christopher	Major small and large bowel procedures with major complications or comorbidities	3/29/14 - 4/11/14	$28,335.20
4	Millit, H. David	Permanent cardiac pacemaker implant without complications or comorbidities	6/16/15 - 6/18/15	$12,519.46
5	Shinn, Lowell	Cardiac arrhythmia and conduction disorders with complications or comorbidities	3/12/17 - 3/22/17	$4,698.70
6	Wolen, John	Stomach, esophageal, and duodenal procedure with major complications or comorbidities	4/12/14 - 4/25/14	$31,122.02
7	Zilles, Michael	Revision of hip or knee replacement without complications or comorbidities	5/18/15 - 5/21/15	$15,842.27

Patient	Referring Physician	Outpatient Principal Diagnosis	Date of Service	Reimbursement
8	Akhavan-Heidari, Mehdi	UNS atherosclerosis extremities	11/25/14	$3,932.07
9	Caruso, Vincent	Cervicalgia	1/8/13	$749
10	Maevsky, Victor	Fitting/adjusting pacemaker	12/16/14	$28,734.75
11	Rahbar, Ahmad	Compression vein	12/19/14	$2,297.01
12	Schmitt, Bradley	Other chest pain	12/30/16	$1,553.56
13	Swamy, Chandra	Mild cervical dysplasia	6/27/18	$1,616.35
14	Tune, Adam	Spondyls without myelopathy or radiculopathy, lumbosacr region	11/27/18	$1,319.82
15	Ybanez-Morano, Jesssica	Malignant neoplasm corpus uteri ex isthmus	6/4/14	$5,096.56

III. Defendants' Scienter

129. At all relevant times, Wheeling Hospital acted knowingly – that is, with actual knowledge, in deliberate ignorance, or with reckless disregard – with respect to the fact that it was submitting false claims to Medicare as alleged here; that it was making false records or statements material to false claims or to get claims paid; and that it was making false records or statements material to an obligation to refund money to the United States, or knowingly concealing or avoiding such an obligation.

130. At all relevant times, Violi and R & V acted knowingly – that is, with actual knowledge, in deliberate ignorance or with reckless disregard – with respect to the fact that they were causing Wheeling Hospital to submit false claims to Medicare as alleged here; that they were causing and making false records or statements material to false claims or to get claims paid; and that they were causing and making false records or statements material to an obligation to refund money to the United States, or knowingly concealing or avoiding such an obligation.

131. At all relevant times, Defendants were familiar with the requirements of the Stark Law, AKS, and FCA, as evidenced, among other things, by their certifications in the Medicare enrollment applications and hospital cost reports described above.

132. Specifically, and among other things, Defendants were familiar with the Stark Law's prohibition on hospitals submitting, and Medicare paying, claims for DHS referred in violation of the statute, 42 U.S.C. §§ 1395nn(a)(1), (g)(1), and the statute's requirement that entities receiving prohibited reimbursements refund those amounts on a timely basis, 42 C.F.R. § 411.353(d).

133. At all relevant times, Defendants acted knowingly – that is, with actual knowledge, in deliberate ignorance, or with reckless disregard – with respect to the fact that the physician compensation arrangements described above did not satisfy the requirements of an applicable exception to the Stark Law.

134. According to its website, R & V holds itself out as a "business consulting and crisis management firm, provid[ing] services to a wide variety of businesses, with particular emphasis on health care." The website touts Violi's and Deluzio's combined "75 years of complex business, financial and legal experience," as well as the firm's "access to additional associates with particular expertise in a number of areas, including . . . government regulation." *See* R & V Associates, www.rvassoc.net (last visited March 25, 2019).

135. R & V's website emphasizes Violi's "Health Care Expertise." From around 1998 to 2005, Violi served as the president and chief executive officer of a Pittsburgh-area pediatric hospital, during which time Deluzio joined that hospital's board of directors. *See* R & V Associates, www.rvassoc.net (last visited March 25, 2019).

136. Since 2012, R & V has managed at least one other acute-care hospital, located in Weirton, WV.

137. Since Violi and R & V took over management of Wheeling Hospital, they required all hospital employees to satisfy annual electronic training and education on the Stark Law and AKS.

138. Based on that training, Wheeling Hospital COO McKeets testified with respect to the Stark Law, that "my understanding would be that you're not to pay or give a piece of – incentivize the physician for increased referrals to the hospital."

139. Asked whether the Stark Law permits "the hospital [to] take into account in hiring someone and setting their salary the facility fees that would be generated for the hospital by the physician," McKeets further testified that "the amount of facility fees would not be related to their compensation."

140. McKeets also testified, with respect to his understanding of the AKS, that "you should not be getting, you know, kickbacks or payments for driving business to your hospital."

141. McKeets testified that these were his understandings throughout the relevant time period, at all times during which he was a Wheeling Hospital executive and his knowledge and actions were imputable to Wheeling Hospital.

142. Violi and R & V shared McKeets's understandings of the Stark Law and AKS, having ordered and overseen the training that was the basis of those understandings.

143. Shortly after taking over management of Wheeling Hospital, Violi cited the need for compliance with the Stark Law as a basis to negotiate higher rental rates in certain physician lease arrangements.

144. On August 20, 2008, McKeets sent a memorandum to Wheeling Hospital's general counsel, Bruce Archer, with the subject line, "Stark II, Phase III Interpretation."

145. In 2011, Ohio Valley Medical Center entered into a settlement with the United States resolving allegations that it had submitted false claims for designated health services to Medicare as a result of compensation arrangements with physicians that did not satisfy any exception to the Stark Law. On information and belief, Defendants were familiar with that matter and resolution.

146. As explained above, on November 27, 2012, Jim Murdy (Wheeling Hospital's CFO) sent an email to COO McKeets and Relator (Wheeling Hospital's Executive Vice President) with a link to an article describing an investigation by the U.S. Department of Justice into whether a Florida Hospital's compensation arrangements with physicians violated the Stark Law.

147. As explained above, shortly after Wheeling Hospital and Dr. Adam Tune entered into their August 2013 arrangement, Murdy expressed concern that the hospital was paying improper compensation to Dr. Tune. Then, in 2015, Bruce Archer, the hospital's general counsel, told Dr. Tune that, for compliance reasons, that contract would need to be amended to remove the provision expressly tying Dr. Tune's incentive bonus to his referral of technical fees to the hospital.

148. As explained above, even after Archer's 2015 discussion with Dr. Tune, the hospital continued to pay Dr. Tune his incentive compensation for several more months. In a 2016 amended contract signed by Violi, the parties removed Dr. Tune's incentive provision, but replaced it with an increase in Dr. Tune's fixed stipend that was intended to and did approximate his lost bonus payments and thus covertly continued to pay Dr. Tune compensation tied to the

volume or value of his DHS referrals to Wheeling Hospital. Defendants made no disclosure to the United States regarding its compensation to Dr. Tune, including the language that it amended for compliance reasons. And even after that revision, Wheeling Hospital continued to pay similar compensation to other physicians, including the employed physicians described above.

149. As the chief decisionmaker and signatory on all physician contracts and amendments, Violi was familiar with the compliance concerns that led to the 2016 restructuring of Dr. Tune's compensation.

150. From 2012 to 2015, Relator repeatedly raised compliance concerns about Wheeling Hospital's physician compensation arrangements to Violi, who disregarded those concerns.

151. Around August 2015, Nicholas Sparchane, a member of Wheeling Hospital's board of directors, asked Relator if the hospital's financial turnaround may have been due in part to regulatory violations. When Relator responded yes, Sparchane said he was not surprised and that he thought that may have been the case.

152. Notwithstanding Violi's and R & V's responsibility for legal and regulatory compliance at Wheeling Hospital; the hospital's purported delegation of that responsibility to them; and all three Defendants' familiarity with the Stark Law, AKS, and FCA, and repeated certifications of Wheeling Hospital's compliance with those statutes, among others, Defendants failed to put into place protocols that would ensure that Wheeling Hospital's financial relationships with its referring physicians and the submission of resulting claims actually did comply with those statutes.

IV. Materiality

153. The fact that Wheeling Hospital's Medicare claims at issue were not permissible under the Stark Law and AKS was material to Medicare's decision whether to pay those claims.

154. Defendants' false representations in their Medicare enrollment forms and cost reports – certifying prospectively and retrospectively that their claims complied with the Stark Law and AKS – were material to Medicare's decision whether to pay Wheeling Hospital's claims; were intended to induce Medicare to pay those claims; were material to Wheeling Hospital's obligation to refund improper reimbursements to the United States; and concealed and avoided that obligation.

155. As demonstrated by their familiarity with the Stark Law and AKS, and by their certifications of compliance therewith, Defendants understood at all times relevant to this lawsuit the above-described materiality of compliance with the Stark Law and AKS and their certifications of compliance therewith.

156. The Stark Law expressly states that hospitals may not bill, and Medicare may not pay, claims for DHS referred in violation of the statute. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1). Further, the accompanying regulations require the timely refund of any payments received in violation of the Stark Law. 42 C.F.R. § 411.353(d).

157. The AKS is a felony statute, the violation of which renders a claim per se false under the FCA. 42 U.S.C. § 1320a-7b(g).

158. As noted above, on its provider enrollment form and elsewhere, CMS classifies compliance with both the Stark Law and AKS as conditions of payment for Medicare claims.

159. Compliance with both the Stark Law and AKS goes to the essence of Medicare's bargain with participating healthcare providers. Both play a key role in ensuring that services are

reasonable and necessary, and not provided merely to enrich the parties to an unlawful arrangement at the expense of federal health programs and their beneficiaries.

160. For these reasons, the United States routinely pursues or settles cases, like this one, alleging that entities and individuals submitted or caused the submission of claims that were false because they violated the Stark Law or AKS.

161. For example, in *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008), the United States obtained a judgment against a hospital executive who knowingly had caused the hospital to submit false claims resulting from referrals by physicians whose compensation arrangements with the hospital violated the AKS and did not satisfy any exception to the Stark Law, including because the compensation paid exceeded fair market value.

162. In *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, Case No. 3:05-cv-02858 (MBS) (D.S.C.), *aff'd*, 792 F.3d 364 (4th Cir. 2015), the United States obtained a judgment against a hospital that had compensation arrangements with physicians that failed to satisfy any exception to the Stark Law, including because the physicians' compensation exceeded the fair market value of their actual services and was determined in a manner that took into account the volume or value of the physicians' referrals of outpatient hospital services.

163. In *United States ex rel. Reilly v. North Broward Hospital District, et al.*, Case No. 10-60590 (S.D. Fla.), the United States settled a case alleging that a hospital had entered into compensation arrangements with certain physicians that did not satisfy any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value.

164. In *United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al.*, No. 12-856 (W.D.N.C), and *United States ex rel. Dorsey v. Adventist Health System Sunbelt*

Healthcare Corp., et al., No. 13-217 (W.D.N.C), the United States settled cases alleging that a hospital had entered into compensation arrangements with physicians that did not satisfy any applicable exception to the Stark Law, including because the compensation paid was determined in a manner that took into account the volume or value of the physicians' referrals.

165. In *United States ex rel. Mayes v. Berkeley HeartLab Inc., et al.*, No. 9:11-CV-01593-RMG (D.S.C.), *United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc., et al.*, No. 1:11-CV-02308 (D.D.C.), and *United States, et al. ex rel. Lutz, et al. v. Health Diagnostic Laboratory, Inc., et al.*, No. 9:14-CV-0230-RMG (D.S.C.), the United States obtained a judgment (appeal pending) against three defendants for paying improper remuneration to physicians to induce them to refer patients for laboratory testing in violation of the AKS.

166. In *United States ex rel. David Felten, M.D., Ph.D. v. William Beaumont Hospitals, et al.*, No. 2:10-cv-13440 (E.D. Mich.), *United States ex rel. Karen Carbone v. William Beaumont Hospital*, No. 11-cv-12117 (E.D. Mich.), *United States ex rel. Cathryn Pawlusiak v. Beaumont Health System, et al.*, No. 2:11-cv-12515 (E.D. Mich.), and *United States ex rel. Karen Houghton v. William Beaumont Hospital*, No. 2:11- cv-14312 (E.D. Mich.), the United States settled cases alleging that a hospital had entered into compensation arrangements with certain physicians that violated the AKS and did not satisfy any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value.

167. The violations alleged here are not minor or insubstantial. Instead, the ways in which Defendants violated the Stark Law and AKS implicate the core concerns of those statutes, including because Defendants directly incentivized and paid physicians in return for increased referrals to Wheeling Hospital. Defendants knowingly and systematically paid compensation to

physicians that resulted in thousands of false Medicare claims, as a result of which Defendants enriched themselves considerably at the expense of the United States.

FIRST CAUSE OF ACTION
(False Claims Act: Presenting and Causing False Claims)
(31 U.S.C. § 3729(a)(1) (claims up to and through May 29, 2009)
and 31 U.S.C. § 3729(a)(1)(A) (claims from and after May 30, 2009))
(All Defendants)

168. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth here.

169. Defendant Wheeling Hospital presented, and defendants Violi and R & V caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims to the Medicare program for reimbursement (examples of which are identified in paragraph 128 above) of services rendered to patients who were referred by Dr. Tune, employed physicians, and Radiology Associates physicians in violation of the Stark Law, and by Dr. Tune in violation of the Anti-Kickback Statute.

170. Defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

171. The United States sustained damages because of Defendants' wrongful conduct.

SECOND CAUSE OF ACTION
(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(2) (claims up to and through June 6, 2008)
and 31 U.S.C. § 3729(a)(1)(B) (claims from and after June 7, 2008))
(All Defendants)

172. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth here.

173. Defendants Wheeling Hospital, Violi, and R & V made, used, and caused to be made or used false records or statements – i.e., the false certifications and representations made and caused to be made by Defendants when submitting the false claims for payments and the false certifications made by Defendants in submitting Wheeling Hospital's enrollment agreements and annual cost reports – to get false or fraudulent claims paid and approved by the United States, and that were material to the United States' payment of the false claims at issue in this case.

174. Defendants' false certifications and representations were made for the purpose of getting false or fraudulent claims paid by the United States, and payment of the false or fraudulent claims by the United States was a reasonable and foreseeable consequence of Defendants' statements and actions.

175. The false certifications and representations made and caused to be made by Defendants were material to the United States' payment of the false claims.

176. Defendants made or caused such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

177. The United States sustained damages because of Defendants' wrongful conduct.

THIRD CAUSE OF ACTION

(False Claims Act: False Records Material to Obligation to Pay)
(31 U.S.C. § 3729(a)(7) (claims up to and through May 29, 2009)
and 31 U.S.C. § 3729(a)(1)(G) (claims from and after May 30, 2009))
(All Defendants)

178. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth here.

179. Defendants Wheeling Hospital, R & V, and Violi made and used or caused to be made or used false records or statements, including Wheeling Hospital's enrollment agreements and annual cost reports, material to an obligation to pay or transmit money to the United States, or knowingly concealed, avoided, or decreased an obligation to pay or transmit money to the United States.

180. Defendants made or caused such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

181. The United States sustained damages because of Defendants' wrongful conduct.

FOURTH CAUSE OF ACTION
(Payment by Mistake)
(Wheeling Hospital, Inc.)

182. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth here.

183. This is a claim for the recovery of monies paid by the United States to defendant Wheeling Hospital (directly or indirectly) as a result of mistaken understandings of fact.

184. The United States paid Wheeling Hospital for claims for services referred by physicians who were in a financial relationship with Wheeling Hospital prohibited by the Stark Law without knowledge of material facts, and under the mistaken belief that Wheeling Hospital was entitled to receive payment for such claims, which were not eligible for payment. The United States' mistaken belief was material to its decision to pay Wheeling Hospital for such ineligible claims. Accordingly, Wheeling Hospital is liable for damages to the United States for the total amount of the payments made in error to Wheeling Hospital by the United States

FIFTH CAUSE OF ACTION
(Unjust Enrichment)
(Wheeling Hospital, Inc.)

185. The United States incorporates by reference all paragraphs of this complaint set out above as if fully set forth here.

186. This is a claim for the recovery of monies by which Wheeling Hospital has been unjustly enriched at the expense of the United States.

187. By directly or indirectly obtaining government funds to which it was not entitled, Wheeling Hospital was unjustly enriched, and is liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor against Defendants as follows:

I. On the First Count under the False Claims Act, against all Defendants, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Second Count under the False Claims Act, against all Defendants, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

III. On the Third Count under the False Claims Act, against all Defendants, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

IV. On the Fourth Count for payment by mistake, against Wheeling Hospital, for the damages sustained and/or amounts by which Wheeling Hospital was paid by mistake or by

which Wheeling Hospital retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

V. On the Fifth Count for unjust enrichment, against Wheeling Hospital, for the damages sustained and/or amounts by which Wheeling Hospital was unjustly enriched or by which Wheeling Hospital retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General
Civil Division

SCOTT W. BRADY
United States Attorney

Dated: March 25, 2019

/s/ Rohith V. Srinivas
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CERTIFICATE OF SERVICE

On March 25, 2019, I caused a true and accurate copy of the foregoing United States' Complaint in Intervention to be filed using the Court's CM/ECF system, which will send an electronic notice of filing to all counsel of record.

/s/ Rohith V. Srinivas
Trial Attorney